K121539

## 1.0 510(k) Summary

As required by 21 CFR Section 807.92(c).

NOV 2 2012


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Date of Preparation: May 23, 2012

Device:

| | |
|---|---|
| Trade name: | Xpert® GBS LB |
| Common name: | Group B Strep Lim broth assay or Xpert GBS LB Assay |
| Type of Test: | Nucleic Acid Amplification System, Group B *Streptococcus* with enriched broth method |
| Classification: | Class I (not exempt) |
| Classification name: | *Streptococcus* species serological reagents |
| Regulation number: | 866.3740 |
| Product code: | NJR |
| Classification Advisory Committee: | Microbiology (83) |

Predicate Devices: Cepheid Smart GBS Assay [510(k) #K062948]

Device Description:

The Cepheid Xpert GBS LB Assay is an automated *in vitro* diagnostic DNA test for the qualitative detection of Group B *Streptococcus* (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated real-time polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. Xpert GBS LB Assay testing is indicated for identification of antepartum GBS colonization with vaginal/rectal swab specimens prepared using an enrichment method in LB broth and then tested in the Xpert GBS LB Assay. The assay is performed on the Cepheid GeneXpert® Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample lysis, nucleic acid purification and amplification, and detection of the target sequence in complex samples using real-time PCR (Polymerase chain reaction) assays. The GeneXpert Instrument System family comprises a GeneXpert Dx instrument (GX-I, GX-IV, GX-XVI), the GeneXpert Dx XVI available with 4, 8, 12, or 16 modules; a GeneXpert Infinity-48, available with 16, 24, 32, 40 or 48 modules, or a GeneXpert Infinity-80 available with 16, 24, 32, 40, 48, 56, 64, 72, or 80 modules. The modules are identical for all instrument systems. The instrument systems also contain a computer, and preloaded software for running tests and viewing the results. The GeneXpert Infinity Systems contain robotic features for cartridge handling. Each module contains a syringe drive for dispensing fluids, an ultrasonic horn for lysing cells or spores, a valve drive for sample movement, and I-CORE® thermocycler for performing real-time PCR and detection.

The Xpert GBS LB Assay includes reagents pre-loaded in the Xpert GBS LB cartridge for the simultaneous detection of the target GBS DNA. A Sample Processing Control (SPC), an Internal Control (IC) and a Probe Check Control (PCC) are also included in the cartridge. The SPC is present to control for adequate processing of the target DNA; the IC is present to monitor the presence of inhibitors in the PCR reaction. The PCC verifies reagent rehydration, PCR-tube filling in the cartridge, probe integrity, and dye stability. The GBS primers and probe detect a target within a 3′ DNA region adjacent to the *cfb* gene of *S. agalactiae*.

After collecting and transporting a swab sample to the laboratory, the swab is placed in Lim broth for enrichment overnight, after which a clean swab (Cepheid part number SDPS-120) dipped into the enrichment broth specimen is transferred to the designated chamber of the cartridge. The GeneXpert Instrument System performs sample preparation by eluting the specimen material from the swab, mixing the sample with the SPC (*Bacillus globigii*) in the form of a bead within the cartridge) and treatment reagent, capturing cellular material on a filter, lysing the cells, and eluting the DNA. The DNA solution is then mixed with dry PCR reagents and transferred into the integrated reaction tube for real-time PCR and detection. The results are interpolated by the GeneXpert Instrument Systems from measured fluorescent signals and embedded calculation algorithms. Results may be viewed and printed. The test process takes approximately 55 minutes. Sample preparation, amplification, and real-time detection are all fully-automated and completely integrated.

Device Intended Use:

The Cepheid Xpert GBS LB Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated real-time polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. Xpert GBS LB Assay testing is indicated as an aid in determining GBS colonization status in antepartum women.

- The Xpert GBS LB Assay is used for antepartum testing on enriched Lim broth cultures of vaginal/rectal swabs after 18-24 hours of incubation.

- The Xpert GBS LB assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

Substantial Equivalence:

The Xpert GBS LB Assay is substantially equivalent to Cepheid's Smart GBS Assay [510(k) #K062948]. Both assays detect Group B *Streptococcus* (GBS) DNA from enriched vaginal/rectal swab specimens. Both assays determine the presence of the target organisms through real-time PCR amplification and fluorogenic target-specific hybridization detection and utilize the same Cepheid I-CORE instrumentation format. Table 5.1 shows the similarities and differences between the Xpert GBS LB Assay and the predicate device.

A prospective multi-center study at three sites was conducted on 719 patients to determine the performance characteristics of the device on the GeneXpert Instrument Systems for detection of GBS colonization in antepartum women from vaginal/rectal swab specimens with Lim broth enrichment. Sensitivity and specificity of the Assay relative to reference culture were compared to the sensitivity and specificity of the predicate device, the Cepheid Smart GBS Assay, relative to reference culture. The test results showed the Xpert GBS LB Assay to be substantially equivalent to the Smart GBS predicate device and the reference culture, the current standard of care.

**Table 5.1**

**Similarities and Differences Between the Xpert GBS LB and the Predicate Device**

| | Xpert GBS LB (Proposed Device) | Predicate: Smart GBS (K062948) |
|---|---|---|
| Regulation no. /Product code | 21 CFR 866.3740 / NJR | Same |
| Device Classification Name | Nucleic Acid Amplification Assay System, Group B *Streptococcus*, enriched broth method | Nucleic Acid Amplification Assay System, Group B *Streptococcus*, Direct Specimen Test and enriched broth method |
| Intended Use | The Cepheid Xpert GBS LB Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated real-time | The Cepheid Smart GBS performed on the Cepheid SmartCycler Dx System is a qualitative in vitro diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA from vaginal/rectal specimens and Lim broth cultures. The test utilizes real-time polymerase chain reaction (PCR) for a unique gene specific |

| | Xpert GBS LB<br>(Proposed Device) | Predicate:<br>Smart GBS (K062948) |
|---|---|---|
| | polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. Xpert GBS LB Assay testing is indicated as an aid in determining GBS colonization status in antepartum women.<br><br>• The Xpert GBS LB Assay is used for antepartum testing on enriched Lim broth cultures of vaginal/rectal swabs after 18-24 hours of incubation.<br><br>• The Xpert GBS LB assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women. | sequence amplification of *Streptococcus agalactiae* recovered from clinical samples and fluorogenic target-specific hybridization for the detection of the amplified DNA.<br>Results from the Smart GBS Assay are intended for use as a method for rapid detection of GBS colonization in antepartum and intraparatum women.<br>• The use of the Smart GBS for intrapartum screening should not preclude the use of other strategies (e.g., antepartum testing). Intrapartum Smart GBS results are useful to identify candidates for intrapartum antibiotic prophylaxis when administration of intravenous antibiotics is not delayed pending results.<br>• The Smart GBS assay does not provide antibiotic susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women. |
| Organism Detection | Group B *Streptococcus* DNA | Same |
| Specimen Type | From 18-24 hour Lim broth cultures of Vaginal/rectal swab | Direct from Vaginal/rectal swab or from 18-24 hour Lim broth cultures |
| Collection and Transport Medium | Cepheid Collection Device or swab in a non- nutritive transport medium | Same |
| Assay Platform | Cepheid GeneXpert Dx System, GeneXpert Infinity-48 System, GeneXpert Infinity-80 System | Cepheid SmartCycler System |

| | Xpert GBS LB<br>(Proposed Device) | Predicate:<br>Smart GBS (K062948) |
|---|---|---|
| Assay Format | Amplification: PCR with I-CORE heating and cooling module.<br><br>Detection: Fluorogenic target-specific hybridization | Same<br><br>Same |
| DNA Target Sequence | 3´ untranslated region of the *cfb* gene | Same |
| Probes | TaqMan® | Same |
| Self-contained system assay | Yes | Yes, after sample preparation which is off-line. |
| Single use | Yes; single-use Cepheid cartridge includes integrated reaction tube | Yes; single-use reaction tubes. |
| Sample preparation | Automated Sample Preparation after swab specimen is placed in Lim broth for 18-24 hours at 35°– 37° C. | Manual sample preparation With enriched option, swab specimen is placed in Lim broth overnight at 37° C. |
| Automated amplification / detection and result interpretation | Yes | Same |
| Time to result | ≤ 55 minutes total after sample addition to cartridge. | ~ 75 minutes total including sample preparation and addition to reaction tube. |
| Built in Lysis control | Yes | N/A, the negative and positive controls do not go through sample preparation steps. |
| External Assay Controls | Materials available, but not required. | Materials available and required. |
| Sample Processing Control | Sample Processing Control;<br>Failures result in single sample repeat. | Uses external controls for sample Processing Control |
| Internal Assay Controls | Sample Processing Control;<br>Internal control;<br>Probe Check (all optical channels)<br>Failures result in single sample repeat. | Internal Control |
| Fluidics | Self-contained | Manual sample preparation |
| Criteria for Ct determination | Primary growth curve | Same |

| | Xpert GBS LB (Proposed Device) | Predicate: Smart GBS (K062948) |
|---|---|---|
| Performance Characteristic* | Enriched method<br>Sensitivity: 99.0%<br>Specificity: 92.4% | Enriched method<br>Sensitivity: 98.8%<br>Specificity: 95.3% |

* as determined in the Cepheid Clinical Study Comparing Xpert and Smart GBS Sensitivity and Specificity relative to culture.

Non-Clinical Studies:

**Analytical Sensitivity (Limit of Detection)**

Studies were performed to determine the analytical limit of detection (LoD) of 11 GBS strains representing nine known serotypes. All GBS strains used were procured from ATCC or CDC. The LoD is defined as the lowest concentration per sample that can be reproducibly distinguished from negative samples with 95% confidence or the lowest concentration at which 19 of 20 replicates were positive. Each strain was tested in replicates of 20 per concentration of bacteria.

The LoD was determined empirically as the lowest concentration that had 19/20 or 20/20 positive results. The LoD point estimates for each strain tested are summarized in Table 5.2. The overall LoD for the assay is 333 CFU/mL.

**Table 5.2: Confirmed LoD – GBS Serotypes**

| Strain ID | Confirmed LoD (CFU/swab) [at least 19/20 positive] | Confirmed LoD (CFU/mL of Lim Broth) [at least 19/20 positive] | LoD Estimate (Logistic Regression) (CFU/swab) | | |
|---|---|---|---|---|---|
| | | | Lower 95% CI | LoD Estimate | Upper 95% CI |
| Serotype Ia | 13 (20/20) | 173 | 8.0 | 10.0 | 14.2 |
| Serotype Ib | 25 (20/20) | 333 | 8.7 | 11.1 | 15.7 |
| Serotype II | 25 (20/20) | 333 | 10.4 | 13.3 | 20.1 |
| Serotype II | 25 (20/20) | 333 | 20.1 | 23.6 | 32.1 |
| Serotype III | 25 (19/20) | 333 | 16.3 | 21 | 35.4 |
| Serotype IV | 25 (20/20) | 333 | 10.7 | 14.4 | 23.7 |
| Serotype IVc | 5 (20/20) | 67 | 2.4 | 3.1 | 4.8 |
| Serotype V | 25 (20/20) | 333 | 14.2 | 18.2 | 26.1 |
| Serotype VI | 25 (20/20) | 333 | 7.6 | 10.4 | 17.8 |
| Serotype VII | 25 (20/20) | 333 | 10.2 | 13.4 | 20.7 |
| Serotype VIII | 10 (20/20) | 133 | 4.3 | 5.6 | 8.4 |

**Analytical Specificity (Exclusivity)**

The analytical specificity of the Xpert GBS LB Assay was evaluated by testing a panel of 100 strains representing 24 Streptococci, 76 other species including strains phylogenetically related to *S. agalactiae*, other microflora (bacteria and yeasts) commonly found in vaginal/anal flora, and human DNA. Replicates of three were tested at concentrations of 4.5 to $9.5x10^8$ CFU/mL or 1.7 - 3.2 McFarland units in Lim broth. The analytical specificity was 100%.

**Interfering Substances Study**

In a non-clinical study, potentially interfering substances that may be present in vaginal/rectal specimens were evaluated directly relative to the performance of the Xpert GBS LB Assay. Potentially interfering endogenous and exogenous substances include, but are not limited to: human amniotic fluid, meconium, serum, urine, fecal material, human blood, lubricating gel, vaginal anti-itch medications, vaginal antifungal medications, anti-diarrheal medications, laxatives, stool softeners, topical hemorrhoid ointments, body oil, body powder, deodorant sprays, enema solutions, and spermicidal foam . Substances were tested at concentrations close to saturation. These substances are listed in Table 5.3 with active ingredients. None of the substances tested had a statistically significant effect on the assay performance. All positive samples were correctly reported as GBS Positive, and all negative samples were correctly reported as GBS Negative.

**Table 5.3: Potentially Interfering Substances in Xpert GBS LB Assay**

| Category | Substance/Supplier | Final Concentration |
|---|---|---|
| Lim broth (Control) | Becton, Dickinson and Company | - |
| Human Amniotic Fluid | New England Life Sciences | 2.0% (v/v) |
| Human Whole Blood (EDTA) | Stanford Blood Center | 2.0% (v/v) |
| Human Whole Blood (NaCitrate) | Stanford Blood Center | 2.0% (v/v) |
| Human Serum | Stanford Blood Center | 2.0% (v/v) |
| Human Urine sample | In-house | 2.0% (v/v) |
| Human Fecal sample | In-house | 0.47% (w/v) |
| Human Meconium sample | LEE BioSolutions | 1.75% (w/v) |
| Personal Lubricant | K-Y® Jelly Personal Lubricant (Personal Products Company, Skillman, NJ) | 1.22% (w/v) |
| Lubricating Gel | AquaGel® Lubricating Gel (Parker Laboratories, Inc., Fairfield, NJ) | 0.57% (w/v) |
| Vaginal Anti-itch Medication | Vagisil Cream | 0.41% (w/v) |
| Vaginal Antifungal Medication | Monistat Cream | 0.29% (w/v) |
| | Yeast Gard (Douche) | 1.89% (w/v) |
| Topical Hemorrhoid Ointments | Preparation H Cream | 0.26% (w/v) |
| Anti-Diarrheal Medications | Pepto Bismol | 1.00% (w/v) |
| | Kaopectate | 1.33% (w/v) |
| Deodorant Powder | Vagisil Powder | 0.31% (w/v) |

| Category | Substance/Supplier | Final Concentration |
|---|---|---|
| Deodorant Suppositories | Norforms Suppositories | 0.30% (w/v) |
| Deodorant Spray | FDS Deodorant Spray | 0.53% (w/v) |
| Body Powder | Gold Bond Powder | 0.40% (w/v) |
| Body Oil | Neutrogena Body Oil | 1.41% (w/v) |
| Spermicidal Foam | Delfen Contraceptive Foam | 0.59% (w/v) |
| Oral Laxatives | Metamucil Fiber Supplement | 0.33% (w/v) |
| | Exlax (Chocolate Pieces) | 0.60% (w/v) |
| | Phillips Milk of Magnesia | 1.78% (w/v) |
| Stool Softener | Dulcolax Suppositories | 0.25% (w/v) |
| Enema Solution | Fleet Enema | 1.93% (w/v) |

### Carry-Over Contamination Study

A study was conducted to demonstrate that single-use, self-contained Xpert GBS LB Assay cartridges prevent carry-over contamination in negative samples run following very high positive samples in the same GeneXpert module. The study consisted of a negative sample processed in the same GeneXpert module immediately following a very high GBS positive sample (roughly $1x10^6$ CFU/swab) Lim broth consisting of GBS serotype II or GBS serotype IV cells. This testing scheme was repeated 20 times on four GeneXpert modules for a total of 88 runs resulting in 40 positive and 48 negative specimens. All 40 positive samples were correctly reported as GBS. All 48 negative samples were correctly reported as GBS negative.

### Reproducibility

A panel of seven specimens with varying concentrations of 2 different GBS strains were tested by 2 operators each in triplicate on 5 different days at three sites (7 specimens x 2 operators x 3 times/ day x 5 days x 3 sites). One lot of Xpert GBS LB Assay was used at each of the 3 testing sites. The three levels were moderate positive (~3-4X LOD), low positive (~1X LOD) and high negative (below LOD). Xpert GBS LB Assays were performed on the GeneXpert Instrument Systems according to the Xpert GBS LB Assay procedure. Results are summarized in Table 5.4.

**Table 5.4: Summary of Reproducibility Results**

| Specimen ID | Site 1 (Infinity-48) | Site 2 (GeneXpert Dx) | Site 3 (Infinity-80) | % Total Agreement by Sample |
|---|---|---|---|---|
| **GBS strain 1 moderate positive** | 100.0% (30/30) | 100.0% (30/30) | 100.0% (30/30) | 100.0% (90/90) |
| **GBS strain 1 low positive** | 100.0% (30/30) | 96.7% (29/30) | 100.0% (30/30) | 98.9% (89/90) |
| **GBS strain 1 high negative** | 73.3% (22/30) | 80.0% (24/30) | 63.3% (19/30) | 72.2% (65/90) |
| **GBS strain 2 moderate positive** | 100.0% (30/30) | 100.0% (30/30) | 100.0% (30/30) | 100.0% (90/90) |
| **GBS strain 2 low positive** | 100.0% (30/30) | 100.0% (30/30) | 100.0% (30/30) | 100.0% (90/90) |
| **GBS strain2 high negative** | 80.0% (24/30) | 83.3% (25/30) | 76.7% (23/30) | 80.0% (72/90) |
| **Negative** | 100.0% (30/30) | 100.0% (29/29)[a] | 100.0% (30/30) | 100.0% (89/89)[a] |

[a]One negative sample had indeterminate result on initial test but was not retested by mistake.

### Instrument System Precision

An in-house precision study was conducted to compare the performance of the GeneXpert Dx and the Infinity-80 instrument systems. A panel of seven specimens with varying concentrations of two different GBS strains was tested on 12 different days by two operators. Each operator conducted four runs of each panel specimen per day on each of the two instrument systems (7 specimens x 4 times/ day x 12 days x 2 operators x 2 instrument systems). One lot of Xpert GBS LB Assay was used for the study. Xpert GBS LB assays were performed according to the Xpert GBS LB Assay procedure. Results are summarized in Table 5.5.

**Table 5.5: Summary of Instrument Precision Results**

| Specimen ID | GeneXpert Dx | Infinity-80 | % Total Agreement by Sample |
|---|---|---|---|
| **GBS strain 1 moderate positive** | 100.0% (96/96) | 100.0% (96/96) | 100.0% (192/192) |
| **GBS strain 1 low positive** | 100.0% (96/96) | 100.0% (96/96) | 100.0% (192/192) |
| **GBS strain 1 high negative** | 77.1% (74/96) | 76.0% (73/96) | 76.6% (147/192) |
| **GBS strain 2 moderate positive** | 100.0% (96/96) | 100.0% (96/96) | 100.0% (192/192) |
| **GBS strain 2 low positive** | 99.0% (95/96) | 97.9% (94/96) | 98.4% (189/192) |
| **GBS strain2 high negative** | 85.4% (82/96) | 82.3% (79/96) | 83.9% (161/192) |
| **Negative** | 100.0% (96/96) | 100.0% (96/96) | 100.0% (192/192) |

### Linearity

A study was conducted to define the reportable range of the Xpert GBS LB Assay and demonstrate a linear relationship between target input and assay output. Linearity was evaluated using ten (10) GBS strains representing the nine (9) known serotypes that ranged in concentration from $1x10^8$ CFU/swab to 10 CFU/swab depending on the serotype. Replicates of 4 were tested at each concentration. Positive and negative controls for Xpert GBS LB were included in the study. The Xpert GBS LB Assay responds linearly over four to five logs ranging from $1x10^8$ CFU/swab to 10 CFU/swab depending on the GBS serotype.

## Clinical Performance Characteristics

### Clinical Performance

Performance characteristics of the Xpert GBS LB Assay were evaluated at three institutions in the U.S. Subjects included individuals whose routine care called for collection of vaginal/rectal swab specimens for GBS testing. For eligible subjects, aliquots of leftover Lim broth sample were obtained for testing with the Xpert GBS LB Assay and reference culture testing, and patient management continued at the site per the standard practice. The Xpert GBS LB Assay performance was compared to culture.

Overall Results

A total of 826 specimens were tested for GBS by the Xpert GBS LB Assay, and culture. The Xpert GBS LB Assay demonstrated a sensitivity and specificity for detection GBS colonization of 99.0% and 92.4%, respectively, relative to culture (Table 5.6).

**Table 5.6: Xpert GBS LB Assay Performance vs. Culture**

| | | Culture | | |
|---|---|---|---|---|
| Xpert GBS | | Pos | Neg | Total |
| | Pos | 189 | 48[a] | 237 |
| | Neg | 2[b] | 587 | 589 |
| | Total | 191 | 635 | 826 |
| | | Sensitivity: | 99.0% (95% CI: 96.3-99.9) | |
| | | Specificity: | 92.4% (95% CI: 90.1-94.4) | |
| | | PPV: | 79.7% (95% CI: 74.1-84.7) | |
| | | NPV: | 99.7% (95% CI: 98.8-100) | |

[a]Testing result by sequencing: 47 of 48 GBS specimens were sequenced, 42 were GBS positive, 5 were GBS negative and one Lim broth was not sequenced.
[b]Testing result by sequencing: 2 of 2 GBS specimens were sequenced, both were GBS negative.

Xpert GBS LB Assays for 98.1% (810/826) of eligible specimens were successful on the first attempt. The indeterminate cases included twelve ERROR results, two INVALID results, and two NO RESULT outcomes. All of the 16 indeterminate cases were retested and yielded valid results upon repeat assay. The overall rate of assay success was 100% (826/826).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Cepheid®
c/o Kerry J. Flom, Ph.D.
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NOV 2 2012

Re: k121539
Trade/Device Name: Xpert® GBS LB
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcal spp. serological reagents
Regulatory Class: Class I
Product Code: NJR, OOI
Dated: October 3, 2012
Received: October 4, 2012

Dear Dr. Flom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

**4.0 Indications for Use Form**

510(k) Number (if known): K121539

Device Name: Xpert® GBS LB

Indications for Use:

The Cepheid Xpert GBS LB Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated real-time polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. Xpert GBS LB Assay testing is indicated as an aid in determining GBS colonization status in antepartum women.

- The Xpert GBS LB Assay is used for antepartum testing on enriched Lim broth cultures of vaginal/rectal swabs after 18-24 hours of incubation.

- The Xpert GBS LB assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

| | | |
|---|---|---|
| Prescription Use ___X____<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121539